

JC01 Rec'd PCT/PTO 01 SEP 2005 T

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)	Art Unit:
JANSSON, John-Olov)	Examiner:
Serial No.: 10/530,866)	Washington, D.C.
Filed: April 11, 2005)	September 1, 2005
For: USE OF GHRELIN FOR)	Docket No.: JANSSON=7
TREATING MALNUTRITION)	
IN GASTRECTOMIZED...)	

INFORMATION DISCLOSURE STATEMENT [IDS]

U.S. Patent and Trademark Office
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Randolph Building
401 Dulany Street
Alexandria, VA 22314

S i r :

This Information Disclosure Statement is submitted in accordance with 37 C.F.R. 1.97, 1.98, and it is requested that the information set forth in this statement and in the listed documents be considered during the pendency of the above-identified application, and any other application relying on the filing date of the above-identified application or cross-referencing it as a related application.

1. This IDS should be considered, in accordance with 37 C.F.R. 1.97, as it is filed:

☐ A. within three months of the filing date of the above-identified national application or within three months of the entry into the national stage of the above-identified international application. See 37 CFR 1.97(b)(1) and (3).

☒ B. before the mailing date of a first office action on the merits. See 37 CFR 1.97(b).

☐ C. after (A) and (B) above, but before final rejection or allowance, and Applicants have made the necessary certification (box "i" below) or paid the necessary fee (box "ii" below). See 37 CFR 1.97(c)(2).

☐ i. Counsel certifies that, upon information and belief, each item of information listed herein was

either (a) cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS or (b) was not cited in a communication from a foreign patent office in a counterpart foreign application and was not known to any individual designated in 1.56(c) more than three months prior to the filing of this IDS.

- [] ii. Credit Card Payment Form, PTO-2038, authorizing payment for the fee set forth in 1.17(p), presently believed to be \$180, is attached.

[] D. after (A), (B) and (C) above, but before payment of the issue fee. Applicant petitions under 37 C.F.R. 1.97(d) for consideration of this IDS. A Credit Card Payment Form, PTO-2038, authorizing payment for the fee set forth in 1.17(p)(1), presently believed to be \$180 is attached. Counsel certifies that, upon information and belief, each item of information listed herein was either (i) cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS or (ii) was not cited in a communication from a foreign patent office in a counterpart foreign application and was not known to any individual designated in 1.56(c) more than three months prior to the filing of this IDS.

[] E. As a submission in accordance with the transitional procedure for limited examination after final rejection pursuant to 37 CFR §1.129(a). Pursuant to MPEP §706.07(g), page 700-66, col. 2 (August 2001), this IDS is treated as if filed with a period set forth in 37 CFR §1.97(b) and considered without the petition and petition fee required by 1.97(d).

[] F. As a submission with or after a request for continued examination under CFR §1.114, and before the mailing of a first office action on the RCE. See 37 CFR §1.97(b)(4).

2. In accordance with 37 C.F.R. 1.98, this IDS includes a list (e.g., form PTO-1449) of all patents, publications, or other

information submitted for consideration by the office, either incorporated into this IDS or as an attachment hereto. A copy of each document is attached, except as explained below.

[] While an IDS filed under §1.97 must contain a "list of all patents, publications or other information submitted for consideration by the Office", see §1.98(a) (1), the only requirement for the list is that it provide the information set forth in §1.98(b). There is no requirement that a form PTO-1449 be used (MPEP §609 merely says that use of this form is "encouraged"). Counsel has used a list provided to him by Applicants, and not transferred the information to a PTO-1449, to avoid the risk of any inadvertent error in transferring the information.

[X] A. Document AA is a U.S. Patent or U.S. Patent Publication, and hence a copy of this document has not been provided. See 37 CFR 1.98(a)(2)(ii).

[] B. Documents _____ are deemed substantially cumulative to documents _____, and, in accordance with 1.98(c), only a copy of each of the latter documents is enclosed.

[] C. Certain documents were previously cited by or submitted to the Office in the following prior application(s), which are relied upon under 35 U.S.C. 120:

[insert serial number/filing date]

Applicants identify these documents by attaching hereto copies of the form PTO-892s and PTO-1449s from the files of the prior applications or a fresh PTO-1449 listing these documents, and request that they be considered and made of record in accordance with 1.98(d). Per 37 CFR 1.98(d), copies of these documents need not be filed in this application. If copies of any of these documents cannot be found in the files of the prior applications, the Examiner is requested to so notify counsel before taking action in this case, so replacement copies can be submitted. While an IDS filed under §1.97 must contain a "list of all patents, publications or other information submitted for consideration by the Office", see §1.98(a) (1), the only

requirement for the list is that it provide the information set forth in §1.98(b). There is no requirement that a form PTO-1449 be used (MPEP §609 merely says that use of this form is "encouraged") and no prohibition on submitting a copy of a form PTO-1449 or form PTO-892 from a prior case. Indeed, the re-use of such forms is desirable as it avoids error in transferring the information, and evidences that the reference was considered in a prior application. A previously accepted PTO-1449, or an examiner-prepared PTO-892, necessarily complies with §1.98(b).

[] 3. Documents _____ are not in the English language. In accordance with 1.98(a)(3), Applicants state:

[] documents _____ already contain an English language abstract, summary or claim set.

[] a publicly available abstract is attached to each of documents ____, and the source of each abstract is indicated thereon.

[] documents ____ are patents or published patent applications for which counterpart English language patents or patent applications exist, and are enclosed, as follows:

<u>Foreign Lang. Doc.#</u>	<u>English Lang. Doc.#</u>
[insert]	[insert]

[] applicants have prepared an English translation of at least the pertinent portions of documents _____, and copies are attached.

[] A concise explanation of the relevance of documents _____ is found in the attached search report from the _____ Patent Office (see reply to Comment 68 in the preamble to the final rules; 1135 OG 13 at 20).

[] A concise explanation of the relevance of documents _____ appears in the present specification.

[] A concise explanation of the relevance of documents _____ is set forth as follows:

[Insert concise explanation of relevance]

4. No explanation of relevance is necessary for documents

in the English language (see reply to Comments 67 and 68 in the preamble to the final rules; 1135 OG 13 at 20).

5. If the month of publication of a nonpatent reference is not stated, it is because it is not apparent from review of the reference. If requested to do so by the Examiner, Applicants will attempt to locate and write to the publisher.

If the publication date of a cited document is set forth only as a publication year, and that year is prior to the year of filing or, if priority is claimed, year of priority of this application, then the particular month of publication is not in issue. Likewise if that publication year is after the year of filing of this application, the month of publication is not in issue.

If the date of publication of a nonpatent reference is stated, then, except as explained below, it is the nominal date stated in the reference, or in a larger document (journal or book) from which the reference was extracted. Applicants reserve the right to challenge this date by contacting the publisher to determine the actual shipment date, or by contacting recipients to determine the receipt dates.

6. Other information being provided for the examiner's consideration follows:

[insert other information]

7. In accordance with 37 C.F.R. 1.97(g) and (h), the filing of this IDS should not be construed as a representation that a search has been made or that information cited is, or is considered to be, material to patentability as defined in §1.56 (b), or that any cited document listed or attached is (or constitutes) prior art. Unless otherwise indicated, the date of publication indicated for an item is taken from the face of the item and Applicant reserves the right to prove that the date of publication is in fact different.

8. The Commissioner is hereby authorized and requested to charge any additional fees which may be required in connection with this paper or credit any overpayment to Deposit Account No.

USSN - 10/530,866

02-4035.

Respectfully submitted,

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FORM PTO-1029 U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICEINFORMATION DISCLOSURE STATEMENT
LIST OF DOCUMENTS CITED BY APPLICANT
(Use several sheets if necessary)

ATTY DOCKET NO: JANSSON=7

SERIAL NO: 10/530,866

APPLICANT: JANSSON, John-Olov

FILING DATE: April 11, 2005

GROUP:

U.S. PATENT DOCUMENTS (include at least patentee, patent number and issue date)

EXAMINER INITIAL		DOCUMENT NUMBER							DATE	PATENTEE	CLASS	SUB- CLASS	FILING DATE IF APPROP.
	AA	20	03	04	0	4	7	2	27 Feb 2003	Larsen, Bjarne Due ; et al.			

FOREIGN PATENT DOCUMENTS (include at least document number, publication date and country)

		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION YES/NO
	AB	9	7	2	3	5	0	8	3 July 1997	PCT			N/A
	AC	1	0	6	0	1	9	0	20 DEC 2000	EP			N/A
	AD	9	9	5	8	5	0	1	18 NOV 1999	PCT			N/A
	AE	0	0	2	6	2	5	2	11 May 2000	PCT			N/A
	AF	1	1	9	7	4	9	6	17 Apr 2000	EP			N/A
	AG	0	1	5	6	5	9	2	9 Aug 2001	PCT			N/A

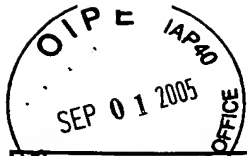
OTHER DOCUMENTS (include author, title, name of publication, volume, pages & date of publication)

	AH	Liedman et al., World J Surg 21, (1997), 416-20, "Changes in Body composition after Gastrectomy: Results of a Controlled Prospective Clinical Trial"
	AI	Fischer et al, Complications of Surgery, In: Schwartz (Ed), Principles of surgery, (1999), Seventh ed, McGraw-Hill, New York, pp 470-472, "Postgastrectomy syndromes"
	AJ	Kojima M, Hosoda H, Date Y, Nakazato M, Matsuo H, Kangawa K, Dec. 1999 Ghrelin is a growth-hormone-releasing acylated peptide from stomach. Nature 402:656-660
	AK	Bowers CY, Momany F, Reynolds GA, Chang D, Hong A, Chang K 1980 Structure-activity relationships of a synthetic pentapeptide that specifically releases growth hormone in vitro. Endocrinology 106:663-667
	AL	Bowers CY, Momany FA, Reynolds GA, Hong A 1984 On the in vitro and in vivo activity of a new synthetic hexapeptide that acts on the pituitary to specifically release growth hormone. Endocrinology 114:1537-1545
	AM	Patchett AA, Nargund RP, Tata JR, Chen MH, Barakat KJ, Johnston DB, Cheng K, Chan WW, Butler B, Hickey G., July 1995 Design and biological activities of L-163,191 (MK-0677): a potent, orally active growth hormone secretagogue. Proc Natl Acad Sci U S A 92:7001-7005
	AN	Smith RG, Cheng K, Schoen WR, Pong SS, Hickey G, Jacks T, Butler B, Chan WW, Chaung LY, Judith F., June 11, 1993 A nonpeptidyl growth hormone secretagogue. Science 260:1640-1643
	AO	Howard AD, et al., August 16, 1996, A receptor in pituitary and hypothalamus that functions in growth hormone release. Science 273:974-977

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if reference considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



FORM PTO 1449 U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE INFORMATION DISCLOSURE STATEMENT LIST DOCUMENTS CITED BY APPLICANT (Use several sheets if necessary)		ATTY DOCKET NO: JANSSON=7	SERIAL NO: 10/530,866
		APPLICANT: JANSSON, John-Olov	
		FILING DATE: April 11, 2005	GROUP:
OTHER DOCUMENTS (include author, title, name of publication, volume, pages and date of publication)			
	AP	Smith RG, et al., Oct. 1997 Peptidomimetic regulation of growth hormone secretion. Endocr Rev 18:621- 645	
	AQ	Asakawa et al., Gastroenterology 120 (Feb. 2001), 337-345, "Ghrelin is an appetite-stimulatory signal from stomach with structural resemblance to Motilin	
	AR	Masuda et al., Biochem Biophys Res. Commun. 276 (2000), 905-908, "Ghrelin stimulates gastric acid secretion and motility in rats"	
	AS	Ariyasu et al., J. Clin Endocrinol Metab 86 (Oct. 2001), 4753-4758, "Stomach is a major source of circulating ghrelin, and feeding state determines plasma ghrelin-like immunoreactivity levels in humans"	
	AT	Dornonville de la Cour et al., Regul. Pept. 99 (2001), 141-150, "A-like cells in the rat stomach contain ghrelin and do not operate under gastrin control"	
	AU	Ankersen et al., Drug Discovery Today, vol. 4, No.11, November 1999, 497-506, "Growth hormone secretagogues: recent advances and applications"	
	AV	Ariyasu et al. "Delayed short-term secretory regulation of ghrelin in obese animals: Evidenced by a specific RIA for the active form of ghrelin, Endocrinology 143(9):3341-3350, Sept. 2002	
	AW	Lehto-Axtelius D., et al. Osteopenia after gastrectomy, fundectomy or antrectomy: an experimental study in the rat. Regul. Pept. 78 (1998), 41-50	
	AX	Date et al. The role of the gastric afferent vagal nerve in ghrelin-induced feeding and growth hormone secretion in rats. Gastroenterology 123 (Oct. 2002), 1120-1128	
	AY	Pinkney et al., Ghrelin gets hungry. The Lancet 359 (April 20, 2002), 1360-1361	
	AZ	Popovic V, et al., Low plasma ghrelin level in gastrectomized patients is accompanied by enhanced sensitivity to the ghrelin-induced growth hormone release. J Clin Endocrinol Metab. 2005 Apr;90(4):2187-91.	
	BA	Dornonville de la Cour C, Lindqvist A, Egecioglu E, Tung YL, Surve V, Ohlsson C, Jansson JO, Erlanson-Albertsson C, Dickson S, Hakanson R. Ghrelin treatment reverses the reduction in weight gain and body fat in gastrectomised mice. Gut., 54:907-913, April 21, 2005.	
	BB	Jeon TY, Lee S, Kim HH, Kim YJ, Son HC, Kim DH, Sim MS. Changes in plasma ghrelin concentration immediately after gastrectomy in patients with early gastric cancer. J Clin Endocrinol Metab. 2004 Nov;89(11):5392-6.	
	BC	le Roux CW, Neary NM, Halsey TJ, Small CJ, Martinez-Isla AM, Ghatei MA, Theodorou NA, Bloom SR. Ghrelin does not stimulate food intake in patients with surgical procedures involving vagotomy. J Clin Endocrinol Metab. 2005 May 24.	
	BD	Tschop M, Smiley DL, Heiman ML. Ghrelin induces adiposity in rodents. Nature. 2000 Oct 19;407(6806):908-12.	
	BE	Wren AM, Small CJ, Ward HL, Murphy KG, Dakin CL, Taheri S, Kennedy AR, Roberts GH, Morgan DG, Ghatei MA, Bloom SR. The novel hypothalamic peptide ghrelin stimulates food intake and growth hormone secretion. Endocrinology. 2000 Nov;141(11):4325-8.	
EXAMINER		DATE CONSIDERED	
EXAMINER: Initial if reference considered. Draw line through citation if not in conformance <u>and</u> not considered. Include copy of this form with next communication to applicant.			